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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,496

Applicant(s)

DOV ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 63-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 5-8, 63-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
2. Applicant's election with traverse of invention VIII, the structure for using in disinfection application in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the inventions are not distinct because they are linked by claims 1 and 10. This is not found persuasive because the presence of linking claims is not a sufficient evidence for non-distinctness. Inventions are distinct as discussed in the prior office action.

3. The claims have been examined insofar as they read on the elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Applicants' election of invention VIII constructively limit the claimed composition to disinfect composition.

Claim Objections

4. Claims 5-8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim 1 recite the nanoparticle was surrounded by media. Claims 5-8 further defined the nanoparticle in physical form other than be surrounded by media. Claims 5-8 define a subject matter outside the scope as defined in claim 1. Since the claims are not read on the elected invention, the claims are withdrawn from further consideration.

Claim Rejections 35 U.S.C. 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4, 9-62 and 93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims recited a nanoparticles with various technique features, such as methylated, with certain percentage of surface groups, with particular IR absorption, with particular protrusions, and with etched interconnected interior channels etc. (see claims 1-63). However, the specification, or the claims fails to provide proper written description as to how to obtain such nanoparticles for practicing the instant claimed invention. One of ordinary skill in the art would be required to perform undue experimentation to make and/or use the invention.

7. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,

- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claim recites nanoparticles with various technique features, such as methylated, with certain percentage of surface groups, with particular IR absorption, with particular protrusions, and with etched interconnected interior channels etc. (see claims 1-63). Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. The claims also recited numerous functional features, such as those recited in claims 14-16, 38-59, fails to provide any guidance, direction, or working examples, as how to realize the claimed function. Nano-technology, particularly, the application in biology and pharmacology, is fairly new to one of ordinary skill in the art. A great effort has been devoted to the development of such technology recently in the art. Many of such works made great contribution in the art and may actually present patentable distinct subject matters (See, e.g., Caruso et al. Science; Wellinghoff et al. , WO 98/13008; Fernandez et al. US application 2001/0051189). Therefore, the art in nano-technology is unpredictable. It is noted that no working example was provided in the specification. In view of the state of the prior art, the relative skill of those in the art, and the unpredictability of the art, applicants have not provide sufficient guidance, or direction and one of ordinary skill of those in the art would not be able to practice the claimed invention without undue experimentation.

8. Claims 1-63 and 93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims recite a biological tissue. However, the specification or the claims provide no information as to what is the biological tissue. One skilled artisan would not be able to practice the claimed invention without the access to the biological tissue. See MPEP 2402, 2403 regarding the rules for deposition of biological materials.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims ^{-4, 9}1-62 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 1 recites a biological media structure. The specification or the claims do not provide a clear definition as to the "structure." Note subject matter eligible to be patented are "process, machine, manufacture, or composition of matter. See, 35 U.S.C. 101. Given broad interpretation, the claims are treated as a composition claims. However, claim as written is confusing as to what subject matter is claimed. Applicants are advised to employ the phrase "composition," or other terms as defined by 35 U.S.C. 101.

12. Claim 1 recite "a three sided biological system," there is no clear definition, or explanation as to what is the 'three-sided' biological system. The claims are indefinite as to the biological system encompassed thereby.

13. The term "substantially," in claim 2, "approximately," in claim 13, 35, "adequately and selectively" in claim 45, "stable," in claim 49, "slow" in claim 57, are relative term which renders the claim indefinite. The terms are not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

14. Claim 59 recites "lock and key" system, the specification or the claims do not provide clear definition of the "lock and key" system. The claim is indefinite as to the system encompassed thereby.

Claim Rejections 35 U.S.C. 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 2, rejected under 35 U.S.C. 102(b) as being clearly anticipated by a yeast tablet. Note objects have three sides are in cylinder, or tablet shape, similar as sphere is one side, and cone has two sides. The yeast tablet comprising yeast (a biological tissue), carrier (surrounding media) and, reasonably expected, particles. Note the particles as recited herein read on any compounds having oxygen atoms.

Claim Rejections 35 U.S.C. 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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18. Claims 14, 9-62 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (US 6,066,328) and Buseti et al. (US 6,190,692) in view of Margulis (WO 97/44278) and Murphy et al. (US 6,399,785).

19. Ribier et al. and Buseti et al. teach that the employment of nanoparticles as controllable release carrier for bioactive ingredients, such as antimicrobial agents is well known in the art. See, particularly, column 5, lines 48-67, and claims 19-20 in Ribier et al; and column 3, lines 15-40, column 5, line 25-30, column 7, lines 20-32 and the claims.

20. The references do not teach expressly that the nanoparticle is hydrated oxide, or the surface of the nanoparticle being modified.

21. However, any compounds containing oxygen could be considered as oxide, and a solid surface in contacting with water would be hydrated. Further, Murphy et al. teach that surface modified nanoparticles are known to be useful for control release purpose. See, particularly, column 5, lines 43-47, column 8, lines 44-47. Margulis et al. teaches an inorganic oxide nanoparticles. See, particularly, the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a antimicrobial disinfection composition comprising nanoparticles such as those disclosed by Margulis et al. or nanoparticles with optimized surface modification.

A person of ordinary skill in the art would have been motivated to make a antimicrobial disinfection composition comprising nanoparticles such as those disclosed by Margulis et al. or nanoparticles with optimized surface modification because nanoparticles, including surface modified nanoparticles, are known to be useful in antimicrobial composition. The particular

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surface modification herein is seen to be an optimization of a result effective parameter, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Note once an antimicrobial disinfection composition is used, the claimed structure including biological tissue, nanoparticles and media would be formed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

A handwritten signature in black ink, appearing to be 'S. Wang' with a stylized flourish at the end.

Shengjun Wang

December 11, 2002